INFORMATION CONTACT. If no one requests an opportunity to testify at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to testify have been heard. Persons in the audience who have not been scheduled to testify, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to testify and persons present in the audience who wish to testify have been heard.

3. Public Meeting

If only one person requests an opportunity to testify at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under **ADDRESSES**. A written summary of each meeting will be made a part of the administrative record.

IV. Procedural Determinations

1. Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive order 12866 (Regulatory Planning and Review).

2. Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State AMLR plans and revisions thereof since each such plan is drafted and promulgated by a specific State, not by OSM. Decisions on proposed State AMLR plans and revisions thereof submitted by a State are based on a determination of whether the submittal meets the requirements of Title IV of SMCRA (30 U.S.C. 1231–1243) and the applicable Federal regulations at 30 CFR Parts 884 and 888.

3. National Environmental Policy Act

No environmental impact statement is required for this title since agency decisions on proposed State AMLR plans and revisions thereof are categorically excluded from compliance with the National Environmental Policy Act (42 U.S.C. 4332) by the Manual of the Department of the Interior (516 DM 6, appendix 8, paragraph 8.4B(29)).

4. Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq*.).

5. Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq*.). The State submittal which is the subject of this rule is based upon Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements established by SMCRA or previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions in the analyses for the corresponding Federal regulations.

List of Subjects in 30 CFR Part 950

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 12, 1995.

John Heider,

Acting Regional Director, Western Regional Coordinating Center.

[FR Doc. 95–12264 Filed 5–17–95; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8–R]

RIN 0720–AA29

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Clarification of the CHAMPUS Definition of Experimental

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This rule proposes to clarify the CHAMPUS definition of ''experimental'' and describes the process that the Office of CHAMPUS follows in determining when an experimental procedure has moved from the status of experimental to the position of nationally accepted medical practice. This clarification is necessary to ensure the CHAMPUS beneficiary and provider population understand the process the Office of CHAMPUS (OCHAMPUS) follows prior to endorsement by CHAMPUS of a new emerging medical technology, drug, or device for which the safety and efficacy have been proven to be comparable or superior to conventional therapies.

DATES: Written public comments must be received on or before July 17, 1995.

ADDRESSES: Forward comments to the Office of the Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS), Program Development Branch, Aurora, CO 80045–6900.

FOR FURTHER INFORMATION CONTACT: Ruth Smith, Program Development Branch, OCHAMPUS, telephone (303) 361–1181.

SUPPLEMENTARY INFORMATION:

A. Discussion of CHAMPUS Policy

Under statutes governing CHAMPUS including 10 U.S.C. 1079, CHAMPUS payments are prohibited for health care services that are ''not medically or psychologically necessary.'' The purpose of this provision, common in health care payment programs, is to prevent CHAMPUS beneficiaries from being exposed to less than fully developed and tested medical procedures and to avoid the associated risk of unnecessary unproven treatment. CHAMPUS regulations and program policies restrict benefits to those procedures for which the safety and efficacy have been proven to be comparable or superior to conventional therapies. In general, the CHAMPUS regulations and program policies exclude cost-sharing of procedures which are experimental or investigational. The evolution of any medical technology or procedure from experimental status to one of national acceptance is often controversial, with those members of the medical community who are using and promoting the procedure arguing that the procedure has national acceptance. In determining whether a procedure is investigational, CHAMPUS uses the following hierarchy of assessment sources:

1. Outcome-based, Phase III trials published in refereed medical literature.

2. Formal technology assessments from nationally recognized technology assessment groups, such as the:

—Agency for Health Care Policy and Research (AHCPR); the

—Emergency Care Research Institute (ECRI); and the

—Food and Drug Administration (FDA).

3. National medical policy organization positions such as the:

—Medical Advisory Panel of the National Blue Cross/Blue Shield Association.

4. National professional medical associations such as those promulgated by the:

—American College of Obstetricians and Gynecologists.

5. National expert opinion organizations such as the

—Diagnostic and Therapeutic Technology Assessment (DATTA) group of the American Medical Association;

—Health Care Financing Administration Technical Advisory Committee; and the

—Office of CHAMPUS Physician Advisory Panel (representing the Uniformed Services Surgeons General). OCHAMPUS has chosen Phase III clinical trials as the test for measuring the safety and efficacy of evolving medical technology procedures. Clinical trials are organized into three phases according to the extent to which a therapy, procedure, drug or device, has progressed in testing. The phase number affixed to a study does not necessarily correspond to the disease stage of patients enrolled in it. For example, in:

Phase I clinical trials, the therapies, procedures, drugs or devices used in this stage of testing have been extensively studied in laboratory and animal tests and are usually now being given to humans for the first time. The aim is to find out how to give a drug or use a procedure, and to make sure that it does not have harmful side effects. Because the side effects in humans are unknown, only a relatively small number of people are allowed to participate.

Therapies, procedures, drugs or devices, that successfully complete Phase I trials then proceed to Phase II clinical trials. Since the therapies, procedures, drugs, or devices were extensively studied in Phase I clinical trials, side effects of each are generally known and more people are included at this phase. Many of the people involved in Phase II clinical trials still have other treatment options available to them if the trial therapy, procedure, drug, or device is not effective for them.

Next, the therapies, procedures, drugs or devices used in Phase II clinical trials move to Phase III clinical trials if each is continuing to demonstrate safety and effectiveness. In this phase the therapy, procedure, drug or device being tested is compared directly with the nationally accepted standard therapy to determine if one is superior to the other, or if one is more effective for specific types or stages of disease. Since reasonable safety and effectiveness have been shown through Phase I and Phase II, many more patients are used in a Phase III clinical trial. Additionally, the patients participating in a Phase III clinical trial usually have not undergone standard treatment. The patients participating in Phase III clinical trials are started on either standard or experimental therapy so the results can be compared. Additionally, instead of focusing on a single agent, some clinical trials study a new drug used in combination with one or more other compounds or other treatments such as surgery or radiation. These clinical trials usually enroll large numbers of people, and often they produce the most dramatic results.

CHAMPUS policy and benefit structure are never based solely on coverage offered by other third party payers, including Medicare, since each operates under different rules and requirements.

B. Need for the Regulation

This proposed rule does not present new agency policy. Rather, it proposes to reaffirm and clarify existing CHAMPUS policy in the body of the CHAMPUS regulation. We propose this primarily in response to a series of U.S. district court decisions concerning one particular experimental treatment, high dose chemotherapy (HDC) with stem cell rescue (SCR) as a treatment for breast cancer (discussed more below), in which the courts held that the CHAMPUS determination regarding this treatment was not sufficiently established to be accepted by the courts. For example, in *Hawkins* v. *Mail Handlers Benefit Plan and CHAMPUS,* Civil No. 1:94CV6, W.D.N.C. (Jan. 28, 1994), the court ruled on a motion for a preliminary injunction filed by a beneficiary of both the Mail Handlers Benefit Plan and CHAMPUS, seeking a court order overruling the exclusion in both plans of coverage for HDC/SCR as a treatment for breast cancer. The court ruled in favor of the Mail Handlers Benefit Plan, but against CHAMPUS based on judgment that the determination that this procedure was experimental was not clearly established by CHAMPUS and was not supported by the beneficiary's evidence.

Similarly, in *Wheeler* v. *Dynamic Engineering Inc., and CHAMPUS,* No. 4.94CV16, E.D.Va. (April 4, 1994), another case of a beneficiary covered by both an employer plan and CHAMPUS who sought a judgment that both should cover HDC/SCR for breast cancer treatment, the court made a distinction between a new company plan that specifically excluded the procedure and the former company plan and CHAMPUS, both of which did not expressly do so. After determining that the former plan was applicable (based on the date the treatment began), the court ruled that neither the plan nor CHAMPUS could properly exclude coverage of the procedure.

OCHAMPUS has carefully reviewed the evidence on HDC/SCR as a treatment for breast cancer. It is our conclusion that it is experimental treatment because on Phase III trials have proven the safety and efficacy of HDC/SCR to be comparable or superior to conventional therapies for breast cancer (and certain other cancers as well), and because formal technology assessment studies have concluded similarly. The CHAMPUS policy regarding the investigational nature of HDC/SCR for breast cancer is based upon four primary sources:

1. The 1988 study entitled ''Public Health Service Reassessment: Autologous Bone Marrow Transplantation'' prepared by the Office of Health Technology Assessment, Agency for Health Care Policy and Research (OHTA/AHCPR) of the Public Health Service, and authored by Harry Handelsman, D.O.; and

2. The American Medical Association Diagnostic and Therapeutic Technology Assessment (AMA DATTA) evaluation of January 1990 entitled ''Autologous Bone Marrow Transplantation 0 Reassessment'' by Elizabeth Brown, M.D.; and

3. The June 1993 study entitled ''Autologous Bone Marrow Transplant and Peripheral Blood Stem Cell Rescue for the Treatment of Breast Cancer'' copyright by ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462; and

4. The most recent ECRI assessment of ''Autologous Bone Marrow Transplant and Peripheral Blood Stem Cell Rescue for the Treatment of Breast Cancer.'' Summary information on this assessment was published in Health Technology Trends in June 1994. OCHAMPUS received a copy of essentially the same material in press

release form directly from ECRI on June 7, 1994. Based upon the information contained in these press releases, OCHAMPUS has requested the purchase of the completed Health Technology Assessment Report from ECRI, a draft which has already been received.

Since the time the 1988 and 1990 reports mentioned above were initially prepared, OCHAMPUS has performed a continuous review of the refereed medical literature on this topic, and has had numerous confirming discussions with the Office of Health Technology Assessment (OHTA) of the Public Health Service regarding their position. The latest of these discussions confirmed the lack of refereed medical literature that would support CHAMPUS coverage of this procedure for the treatment of breast carcinoma. Therefore, although the initial policy classifying HDC/SCR as investigational under CHAMPUS was based upon literature and technical assessments dating from the 1988–1990 time-frame, OCHAMPUS has continually monitored the development of the literature and the status of ongoing Phase III trials regarding the safety and effectiveness of this form of treatment for breast carcinoma and other carcinomas for which it is not currently authorized as a CHAMPUS benefit. The June 1993 formal assessment by ECRI provides independent reconfirmation of the CHAMPUS position. This independent reconfirmation has been substantially bolstered by the most recent ECRI studies which indicate that ''results from the experimental procedure are not any better than published results for conventional therapy to treat breast cancer,'' and that ''the impetus for this (treatment) is more political than scientific * * * (It) is a treatment that's becoming mandated by popular opinion.'' This most recent information reconfirms, in even stronger terms and with newer studies and literature, the earlier conclusions of previous technology assessments that HDC/SCR is experimental in the treatment of breast cancer. To date there has been no new evidence which would warrant a departure from the original coverage determination to exclude CHAMPUS cost-sharing of this procedure as investigational for the treatment of breast carcinoma. The CHAMPUS position is further supported by the Consensus Conference on Intensive Chemotherapy Plus Hematopoietic Stem Cell Transplantation in Malignacies (Journal of Oncology, Volume 12, Number 1, (January 1994); pages 226–231; (Attachment 5) which states in part:

* * * ''Although there is currently insufficient evidence to justify the use of HDC/plus HSC (Hematopoietic Stem Cell) transplantation outside the setting of clinical trial for any stage of breast cancer, there is ample scientific background for vigorous clinical investigation in this important area * * *''.

Based on the evidence regarding this procedure, which demonstrates that it is experimental, and the series of recent court rulings declining to follow an exclusion not clearly established in the governing instruments of the program, we believe this rule is necessary to reaffirm and clarify CHAMPUS policy on experimental procedures and to specifically list a number of procedures we have determined are experimental.

C. Provisions of the Proposed Rule

The proposed rule describes the criteria we use to identify the experimental nature of procedures, drugs, devices, includes a partial list, and makes provision for promptly treating a drug, device or procedure as no longer experimental when the scientific evidence supports that view and the resultant. Any change to the partial list will be published as a notice in the **Federal Register**.

In emphasizing refereed medical literature as the primary source of persuasive evidence that a particular procedure's safety and efficacy have been proven to be comparable or superior to conventional therapies for widespread use, we also underscore our support for committed efforts to advance medical research. A number of military medical centers are engaged in such research protocols. In addition, we are beginning a new DoD demonstration project, under the authority of 10 U.S.C. 1092, to authorize payments for experimental treatments provided to CHAMPUS beneficiaries under certain government approved phase III clinical protocols. Initially, the demonstration project will apply to clinical trials under approved National Cancer Institute protocols for high dose chemotherapy with stem cell rescue for breast cancer treatment.

D. Regulatory Procedures

Executive Order 12866 requires certain regulatory assessments for any ''significant regulatory action,'' defined as one which would result in an annual effect on the economy of $100 million or more, or have other substantial impacts.

The Regulatory Flexibility Act (RFA) requires that each federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues regulations which would have significant impact on a substantial number of small entities.

This proposed rule is not a significant regulatory action under Executive Order 12866. This proposed rule will not involve any significant burden on the CHAMPUS beneficiary or provider population. This proposed rule only clarifies the CHAMPUS definition of experimental and describes the process that OCHAMPUS follows in determining for purposes of benefit coverage when an experimental procedure, drug, or device has moved from the status of experimental to the position of nationally accepted medical practice. This proposed rule does not impose information collection requirements on the public under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3511).

This is a proposed rule. Comments from all interested parties are solicited.

List of Subjects in 32 CFR Part 199

Claims, Handicapped, Health insurance, Military personnel.

Accordingly, 32 CFR Part 199 is proposed to be amended as follows:

1. The authority citation for Part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.2 is amended in paragraph (b) by revising the definition of ''Experimental'', removing the Note following the definition of ''Experimental'' and adding the definitions for ''Rare diseases'' and ''Unlabelled or off labeled drugs'' in alphabetical order to read as follows:

§ 199.2 Definitions.

* * * * *

(b) * * *

Experimental. A drug, device, or medical treatment or procedure is experimental or investigational;

(1) If the drug or device cannot be lawfully marketed without approval of the Untied States Food and Drug Administration (FDA) and approval for marketing has not been given at the time the drug or device is furnished to the patient; or

(2) If reliable evidence shows that the drug, device, or medical treatment or procedure is the subject of ongoing Phase I, II, or III clinical trials or is under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy as compared with the standard means of treatment or diagnosis; or

(3) If reliable evidence shows that the consensus of opinion among experts regarding the drug, device, or medical

treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, or its efficacy as compared with the standard means of treatment or diagnosis. (See Exclusions and limitations, ''Not in accordance with accepted standards, experimental or investigational'' in § 199.4 for procedures in determining experimental.)

* * * * *

Rare diseases. CHAMPUS defines a rare disease as one which affects fewer than one in 200,000 Americans.

* * * * *

Unlabelled or off labeled drugs. Medications that are otherwise Food and Drug Administration (FDA) approved for general use in humans. The drug must be medically necessary for the treatment of the condition for which it is administered, according to accepted standards of medical practice.

* * * * *

3. Section 199.4 is amended by revising paragraph (g)(15) as follows:

§ 199.4 Basic program benefits.

* * * * *

(g) *Exclusions and limitations.* * * * * * * * *

(15) *Not in accordance with accepted standards, experimental, or investigational.* Among the services excluded from CHAMPUS program benefits on the grounds that they are not medically or psychologically necessary are services and supplies not provided in accordance with accepted professional medical standards, or related to essentially experimental or investigational procedures or treatment regimens. (See the definition of ''experimental'' in § 199.2.)

(i) *General.* For the purpose of determining experimental:

(A) The term reliable evidence shall mean only:

(*1*) Outcome-based, Phase III trials published in refereed medical literature.

(*2*) Published formal technology assessments.

(*3*) The published reports of national professional medical associations.

(*4*) Published national medical policy organization positions.

(*5*) The published reports of national expert opinion organizations.

(B) The order given in the iteration of sources of evidence in paragraph (g)(15)(i)(A) of this section is in the order of the relative weight to be given to any particular source. Only those reports and articles containing scientifically validated data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence. Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, or medical treatment or procedure as their personal treatment or procedure of choice or standard of practice.

(C)(*1*) Use of drugs and medicines and devices not approved by the FDA for commercial marketing, that is, for general use by humans (even though permitted for testing on human beings) is considered experimental. Drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered under CHAMPUS as if FDA approved. Certain cancer drugs, designated as Group C drugs (approved and distributed by the National Cancer Institute) and Treatment Investigational New Drugs (INDs), cannot be cost-shared under CHAMPUS because they are not approved for commercial marketing by the FDA. However, medical care related to the use of Group C drugs and Treatment INDs can be cost-shared under CHAMPUS when the patient's medical condition warrants their administration and the care is provided in accordance with generally accepted standards of medical practice. In areas outside the United States, standards comparable to those of the FDA are the CHAMPUS objective.

(*2*) CHAMPUS can consider cost-sharing ''unlabelled or off label'' uses of medications that are otherwise approved by the FDA for general use in humans. Approval for cost-sharing of ''off label or unlabelled'' indications requires review for medical necessity, and also requires demonstrations from medical literature, national organizations, and/or technology assessment bodies that the ''off label or unlabelled'' usage of the drug is safe, effective, and a nationally accepted standard of practice in the medical community.

(D) CHAMPUS benefits for a rare disease are reviewed on a case-by-case basis by the Director, OCHAMPUS, or designee. In reviewing the case, the Director, OCHAMPUS, or designee may consult with any or all of the following sources to determine if the proposed therapy is considered safe and effective:

(*1*) Trials published in refereed medical literature.

(*2*) Formal technology assessments.

(*3*) National medical policy organization positions.

(*4*) National professional associations.

(*5*) Regional expert opinion organizations.

(*6*) Individual and small group expert opinion.

(ii) *Care excluded.* This exclusion includes all services directly related to the experimental or investigational procedure. However, CHAMPUS may cost-share services or supplies when there is no logical or causal relationship between the experimental or investigational procedure and the treatment at issue or where such a logical or causal relationship cannot be established with a sufficient degree of certainty. This CHAMPUS cost-sharing is authorized in the following circumstances:

(A) Treatment that is not related to the investigational or experimental procedure; e.g., medically necessary in the absence of the experimental or investigational treatment.

(B) Treatment which is a necessary follow-on to the experimental or investigational procedure but which might have been necessary in the absence of the experimental or investigational treatment.

(iii) *Examples of experimental procedures.* This paragraph consists of a partial list of experimental or investigational procedures. Such procedures are excluded from CHAMPUS program benefits. This list is not all inclusive. Other experimental procedures, as defined in § 199.2, are similarly excluded, although they do not appear on this partial list. With respect to any procedure included on this partial list, if and when the Director, OCHAMPUS determines that based on the standards established in the definition of ''experimental'' in § 199.2, such procedure is no longer experimental or investigational, the Director will initiate action to remove the procedure from this partial list of experimental procedures. From the date established by the Director as the date the procedure became no longer experimental until the date the regulatory change is made to remove the procedures from the partial list of experimental procedures, the Director, OCHAMPUS will suspend treatment of the procedure as an experimental procedure. Following is the non-inclusive, partial list of experimental procedures, all of which are excluded from CHAMPUS benefits:

(A) Radial keratotomy (refractive keratoplasty).

(B) Cellular therapy.

(C) Histamine therapy.

(D) Stem cell assay, a laboratory procedure which allows a determination to be made of the type and dose of

cancer chemotherapy drugs to be used, based on in vitro analysis of their effects on cancer cells taken from an individual.

(E) Topical application of oxygen.

(F) Immunotherapy for malignant disease.

(G) Prolotherapy, joint sclerotherapy, and ligamentous injections with sclerosing agents.

(H) Transcervical block silicone plug.

(I) Whole body hyperthermia in the treatment of cancer.

(J) Portable nocturnal hypoglycemia detectors.

(K) Testosterone pellet implants in the treatment of females.

(L) Estradiol pellet implants.

(M) Epikeratophakia for treatment of aphakia and myopia.

(N) Bladder stimulators.

(O) Ligament replacement with absorbable copolymer carbon fiber scaffold.

(P) Intraoperative radiation therapy.

(Q) Gastric bubble or balloon.

(R) Single and dual photon absorptiometry for the detection and monitoring of osteoporosis.

(S) Dorsal root entry zone (DREZ) thermocoagulation or microcoagulation neurosurgical procedure.

(T) Brain electrical activity mapping (BEAM).

(U) Topographic brain mapping (TBM) procedure.

(V) Ambulatory blood pressure monitoring.

(W) Bilateral carotid body resection to relieve pulmonary symptoms.

(X) Intracavitary administration of cisplatin for malignant disease.

(Y) Cervicography.

(Z) Ambulatory home monitoring—uterine contractions.

(AA) Sperm evaluation, hamster penetration test.

(BB) Transfer factor (TF).

(CC) Continuous ambulatory esophageal pH monitoring (CAEpHM) is considered investigational for patients under age 12 for all indications, and for patients over age 12 for sleep apnea.

(DD) Adrenal-to-brain transplantation for Parkinson's disease.

(EE) Videofluoroscopy evaluation in speech pathology.

(FF) Herniography.

(GG) Applied kinesiology.

(HH) Hair analysis to identify mineral deficiencies from the chemical composition of the hair. Hair analysis testing may be reimbursed when necessary to determine lead poisoning.

(II) Iridology (links flaws in eye coloration with diseases elsewhere in the body).

(JJ) Small intestinal bypass (jejunoileal bypass) for treatment of morbid obesity.

(KK) Biliopancreatic bypass.

(LL) Gastric wrapping/gastric banding.

(MM) Calcium EAP/calcium orotate and selenium (also known as Nieper therapy)—Involves inpatient care and use of calcium compounds and other non-FDA approved drugs and special diets. Used for cancer, heart disease, diabetes, and multiple sclerosis.

(NN) Percutaneous balloon valvuloplasty for mitral and tricuspid valve stenosis.

(OO) Amniocentesis performed for ISO immunization to the ABO blood antigens.

(PP) Balloon dilatation of the prostate.

(QQ) Helium in radiosurgery.

(RR) Palladium ^{103}Pd) seed brachytherapy.

(SS) Electrostimulation of salivary production in the treatment of xerostomia secondary to Sjorgren's syndrome.

(TT) Interaoperative monitoring of sensory evoked potentials (SEP). To include visually evoked potentials, brainstem auditory evoked response, somatosensory evoked potentials during spinal and orthopedic surgery, and sensory evoked potentials monitoring of the sciatic nerve during total hip replacement. Recording SEPs in unconscious head injured patients to assess the status of the somatosensory system. The use of SEPs to define conceptional or gestational age in preterm infants.

(UU) Autolymphocyte therapy (ALT) (immunotherapy used for treating metastatic kidney cancer patients).

(VV) Radioimmunoguided surgery in the detection of cancer.

(WW) HLA–DNA typing.

(XX) Gait analysis (also known as a walk study or electrodynogram).

(YY) Cryosurgery for liver metastases.

(ZZ) Use of cerebellar stimulators/pacemakers for the treatment of neurologic disorders.

(AAA) Signal-averaged ECG.

(BBB) Intraventricular administration of narcotics.

(CCC) Peri-urethral Teflon injections to manage urinary incontinence.

(DDD) Extraoperative electrocorticography for stimulation and recording in order to determine electrical thresholds of neurons as an indicator of seizure focus.

(EEE) Quantitative computed tomography (QCT) for the detection and monitoring of osteoporosis.

(FFF) Percutaneous transluminal angioplasty in the treatment of obstructive lesions of the carotid, vertebral and cerebral arteries.

(GGG) Endoscopic third ventriculostomy.

(HHH) Holding therapy—Involves holding the patient in an attempt to achieve interpersonal contact, and to improve the patient's ability to concentrate on learning tasks.

(III) In utero fetal surgery.

(JJJ) Light therapy for seasonal depression (also known as seasonal affective disorder (SAD)).

(KKK) Transurethral laser incision of the prostrate (TULIP).

(LLL) Contigen Bard® collagen implant.

(MMM) Dorsal column and deep brain electrical stimulation of treatment of motor function disorder.

(NNN) Chelation therapy, except under specific conditions.

(OOO) All organ transplants *except* heart, heart-lung, lung, kidney, some bone marrow, liver, liver-kidney, corneal, and heart-valve.

(PPP) Implantable infusion pumps, *except* for hepatic artery perfusion chemotherapy for the treatment of primary liver cancer or metastatic colorectal liver cancer.

(QQQ) Services related to the candidiasis hypersensitivity syndrome, yeast syndrome, or gastrointestinal candidiasis (i.e., allergenic extracts of Candida albicans for immunotherapy and/or provocation/neutralization).

(RRR) Treatment of chronic fatigue syndrome.

(SSS) Extracorporeal immunoadsorption using protein A columns for conditions other than acute idiopathic thrombocytopenia purpura.

(TTT) Dynamic posturography (both static and computerized).

(UUU) Laparoscopic myomectomy.

(VVV) Growth factor, including platelet-derived growth factors, for treating non-healing wounds. This includes procuremen®, a platelet-derived wound-healing formula.

(WWW) High dose chemotherapy with stem cell rescue (HDC/SCR) for any of the following malignancies:.

(*1*) Breast cancer.

(*2*) Ovarian cancer.

(*3*) Testicular cancer.

(*4*) Multiple myeloma.

* * * * *

Dated: May 11, 1995.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 95–12031 Filed 5–17–95; 8:45 am]

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